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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,367

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Jurgen Hemberger

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EXAMINER

DESAI, ANAND U

ART UNIT

PAPER NUMBER

1656

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DELIVERY MODE

06/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/506,367	Applicant(s) HEMBERGER ET AL.	
	Examiner ANAND U. DESAI	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37,43-49 and 51-73 is/are pending in the application.
- 4a) Of the above claim(s) 56-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37,43,44,46-48 and 51-55 is/are rejected.
- 7) ☒ Claim(s) 45 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20080428</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 24, 2008 has been entered.
2. Claims 56-73 have been withdrawn previously.
3. Claims 37, 43-49, and 51-55 are currently pending and are under examination.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on April 28, 2008 is being considered by the examiner.

Withdrawal of Rejections

5. The rejection of claims 37, 43-49, 51-53, and 55 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37-50, 54, 56, and 74-78 of copending Application No. 10/506,366 (US 2006/0217293 A1) is withdrawn based on the approval of a terminal disclaimer (Repeated from Advisory action for clarity of claims status).
6. The rejection of claims 37 and 43-55 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on the amendment to the claims.

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7. The rejection of claims 37 and 43-55 under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for any hydroxyalkyl starch protein conjugate is withdrawn based on the amendment to the claims drawn to a hydroxyethylstarch-protein conjugate and the remarks filed March 24, 2008 discussing the different coupling disclosed.

8. The rejection of claims 37, 43, 44, 46, 51-53, and 55 under 35 U.S.C. 102(b) as being anticipated by Leonard et al. (U.S. Patent 5,079,337) is withdrawn based on the amendment and remarks about a single covalent bond between the hydroxyethylstarch-protein conjugate (Repeated from Advisory action for clarity of claims status).

Maintenance of Objections and Rejections

Claim Rejections - 35 USC § 102/Claim Rejections - 35 USC § 103

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 37, 43, 44, 46-48, and 51-55 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Adamson (U.S. Patent 6,500,930 B2).

Adamson discloses a hemoglobin-polysaccharide conjugate, wherein the polysaccharide is hydroxyethyl starch. The process for preparing a reduced hemoglobin-polysaccharide conjugate composition comprising: (a) subjecting a starting polysaccharide to oxidative ring-opening to produce an oxidatively ring-opened polysaccharide carrying aldehyde groups; (b) reacting said oxidatively ring-opened polysaccharide with a hemoglobin under conditions suitable to form schiff base linkages between the hemoglobin and the ring-opened

polysaccharide to form an initial hemoglobin-polysaccharide conjugate composition; (c) degrading the oxidatively ring-opened polysaccharide by maintaining the conjugate composition under controlled conditions of aqueous solution with predetermined pH for a period of time until a desired lower average molecular weight hemoglobin-polysaccharide composition as compared to the initial hemoglobin-polysaccharide composition is reached to form a detectably degraded further hemoglobin-polysaccharide conjugate composition with a lowered average molecular weight, a lowered amount of unreacted hemoglobin species and narrowed molecular weight distribution as compared to said initial hemoglobin-polysaccharide conjugate composition; and (e) recovering said reduced hemoglobin-polysaccharide conjugate composition. Adamson does not disclose the conjugation of the enzymes recited in the Markush group of claim 54, but it would have been obvious to the person having ordinary skill in the art to use any protein sequence with a reactive amino group in a Schiff's base chemical reaction, because the Schiff's chemical reaction was well known in the art.

Applicant is referred to MPEP 2113 Product-by-Process Claims. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). “The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature” than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180

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USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983).

Conclusion

14. Claims 45 and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Suggest in claim 37 reciting "...a single covalent bond which results from a coupling of the terminal aldehyde....".

16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947.

The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 6, 2008

/Anand U Desai, Ph.D./
Patent Examiner, Art Unit 1656